

# NeuroMuscular Consultants

A Medical Corporation

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November 30, 1999

Document Management Branch (HFA-305)

Food and Drug Administration

5630 Fishers Lane

Room 1061

Rockville, MD 20852

**Re: Docket No. 97N-484F**

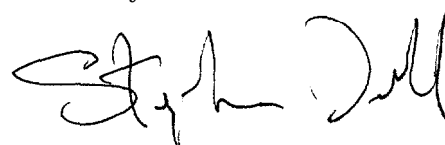
Dear Sir or Madam:

I write you in regard to the proposed FDA regulation which could allow the FDA to regulate some types of allograft as medical devices. I am fearful that such regulations, if imposed, will require bone banks to satisfy FDA pre-market requirements, such as sponsoring clinical trials and submitting lengthy regulatory documents. These we are clearly in no position to provide, and such regulation will predictably lead to a curtailed supply of bone products. We rely on such products for treating patients and the potential implications of FDA regulatory action are frightening.

I would urge you to not accept the aforementioned proposed regulation.

Should you have any further comments or questions, please do not hesitate to contact me at the above address and telephone number.

Sincerely,



Stephen Dell, M.D.

Neurosurgeon

SD:blp

97N 484S

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